on media to dispute sofosbuvir price considered as scandalous, while compliant with French regulation. French Health Minister organized a European coalition to control its price. Under tremendous media, political and administrative pressure, the manufacturer accepted significant price decrease, early entry agreement in France and later in most EU countries. Following this saga, to ensure drug budget will remain under control, most EU countries issued regulation or law to cap drug budget expenditure for HCV. **CONCLUSION:** This case highlights limit of current pricing policies which are unable to match affordability and drug prices. Even if cost effectiveness remains important information for efficiency assessment, sofosbuvir case confirms the inability of cost-effectiveness analysis to address affordability issue. Budget impact in supporting decision making will become more and more critical in the future.

PHP340

IS ONCOLOGY DRUG FINANCIAL TOXICITY A SPECIFIC US ISSUE?

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BACKGROUND: Cancer imposes enormous financial burden to society. Direct medical costs were estimated at around €51 billion across European (EU) countries (2009) and $88.7 billion in the United-States (US) (2011). The concept of "financial toxicity" has been first reported by US academic oncologists, Zafar and Abernathy in 2013. It refers to financial distress linked to out-of-pocket payments of costly oncology drugs (OD). This critical concept led to the development of a patient-reported outcome questionnaire by de Souza et al. This conceptual research aimed to address aspects of oncology drug financial toxicity (ODFT) and how the US and European Union countries cope with high OD prices. **DISCUSSION:** ODFT has been reported to affect patient's quality of life and treatment adherence. In US, ODFT is related to the positioning in specialty care tier (fourth or fifth tier), leaving a high co-pay for the patients. Moreover, 13% of the US population is uninsured (2013). This issue is not new; in 2007, a study reported that 16% of oncologist did not propose expensive products to some patients based on their perception of patient affordability. In EU, the coverage system is quite different and operates as an on/off system, protecting patients from ODFT. Patients are either 100% covered for all reimbursed drugs (France, UK, Germany, Spain, Italy), or drugs are not recommended/reimbursed and then not proposed to the patients nor requested by the patients. The level of availability of these treatments might substantially differ between countries; high access of cancer drugs seen in France and Germany, while more restricted access seen in Spain, Italy and the UK. **CONCLUSIONS:** EU inhabitants will remain protected from ODFT as long as reimbursement process remains an on/off system (100% or 0% coverage) and off-reimbursement use is exceptional. ODFT will remain specific to the US and possibly to emerging countries.

PHP341

THE SOUTH AFRICAN GUIDELINES FOR PHARMACOECONOMIC SUBMISSIONS: A REVIEW IN CONTEXT OF EXISTING LEGISLATION AND CHALLENGES TO IMPLEMENTATION

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BACKGROUND: The South African Pharmacoeconomic Guidelines were published in February 2013, with the intention for application to newly approved medicines in the privates sector. However, uptake has been poor and the number of submissions negligible. **OBJECTIVES:** This study aims to examine the pharmacoeconomic guidelines in the context of existing legislation, policy and incentives in the private sector in South Africa to make explicit the reasons for the poor uptake and challenges to implementing the guidelines. **METHODS:** A review of existing legislation regulating reimbursement of medicines in the private sector was undertaken in relation to the implementation of the guidelines, as well as interviews with key stakeholders in the pharmaceutical industry, ministry of health and health insurance industries to understand attitudes to and challenges to adopting the guidelines submission criteria and results. **RESULTS:** Existing legislation means that results of pharmacoeconomic submissions are not enforceable – funders are not required reimburse for products should the ministry of health evaluations process deem them cost-effective. Pharmaceutical companies are thus at risk of a negative finding on reimbursement with no assurance that a positive finding will improve reimbursement for new products. As submission is currently not mandatory, this is something they will be unlikely to do. The level of strict application or flexibility within the requirements of the guidelines is also not clear. **CONCLUSIONS:** Uptake and engagement with the South African Pharmacoeconomic Guidelines has been poor, with no submissions formally evaluated since the guidelines were finalised. Several existing policy and legislative barriers exist which make the success of these guidelines in this current environment unlikely. Building capacity for submitting analyses as well as within the ministry of health to evaluate submissions will be critical.

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NEED FOR NEW PHARMACOECONOMICS POLICY FOR REGULATING PRICES OF MEDICAL DEVICES IN INDIA

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In India, medical device industry is a multi-product industry covering the entire gamut from disposable gloves and syringes to high-end machines like CT scans and robotic surgery machines and worth $5 billion approximately growing at a Compound Annual Growth Rate (CAGR) of 15%. Over 75% of medical devices market is dependent on imports, mostly by multinationals that have no manufacturing facility in India. According to a survey conducted by us, the disposables ($1.57 billion), consumables ($0.83 billion) and surgical instruments ($0.06 billion) market depends on around 40-50% of imported products while the medical electronics ($1.57 billion), hospital equipments ($0.39 billion), implants ($0.20 billion) and diagnostics ($0.09 billion) categories on around 85-90%. Due to more dependency on imported products as well as absence of regulations for prices in India, doctors, hospitals and retailers overcharged the patients almost three to four times for certain devices e.g. Drug eluting stents (DES) manufactured by Abbott imported at $640 and sold at $2000, a mark-up of over 250% and that manufactured by Medtronics imported at $485 and sold at $2600, a mark-up of more than 400%. Recognising this policy deficit, the Department of Pharmaceuticals under the Ministry of Chemicals & Fertilizers, has published draft proposals which is National Medical Device Policy-2015 for the medical devices approval & pricing regulations. These proposals have recommended creating an autonomous body, the National Medical Devices Authority (NDMA) for pricing control of medical devices by including them under the Essential Commodities Act or through a Medical Devices Prices Control Order(MDPCO) and creating a separate pricing division in the National Pharmaceuticals Pricing Authority(NPPA). Ispor-India chapter has developed Pharmacoeconomic guidelines which will also include the above mentioned devices and the same will be presented in this presentation along with our survey data.

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PRICING AND REIMBURSEMENT POLICIES OF TURKEY AND UKRAINE

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Recently, the need for health services has increased gradually and the limitations in sources allocated for this area have been recognized.According to Danzon (2001), arrangements towards controlling the expenses through price,profit controls and reimbursement methods This study examines;current situation in Turkey and Ukraine, pharmaceutical pricing methods, reimbursement methods and basic health indicators within the scope of changing pharmaceutical policies in Turkey and Ukraine. It was detected that the pharmaceutical pricing in Turkey has been performed on the basis of the reference pricing system that takes Italy,Portugal,Spain,Greece and France as reference. The regulations regarding the reimbursement process are determined by SSI. In Ukraine there are margin control and reference pricing methods only for the medicines that may be public purchased and are included in the National list of medicines and the list of medicines "On the procedure of procurement of medicines by health institutions financed from the public budget". Reimbursement method was applied only for one pilot project on antihypertensive medicines in 2012 because state health insurance system has not yet implemented. Due to the resolution of Cabinet of ministers of Ukraine "On reference pricing for medicines and medical products, purchased by the state and local budgets reference pricing is implemented for medicines, which are included in the list of medicines that have margin control and may be purchased within public budgets. Reference pricing is based on the international comparison with prices in mainly eastern Europe countries. Coverage of government was 13% of the Ukrainian pharmaceutical market The reimbursement system of Turkey has been changed numerous times and the discount rates has incrementally risen. Ukraine has just began implementing pricing and reimbursement for medicines. It is understand that Turkey has been done policies already but Ukraine has just began implementations. Our study shows impact of Turkish reforms and expected from Ukraine.

PHP344

HEALTH PROFFESSIONALS INVOLVEMENT IN POLITICS A MEANS TO IMPROVING HEALTHCARE DELIVERY AND HEALTHCARE LEGISLATIONS FOR HEALTHCARE SEEKERS IN AFRICA

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OBJECTIVES: Health Professionals in Africa in an attempt to improve healthcare delivery have brought up well thought out ways to offer better health care service, but for their lack of involvement in Politics and Legislation in their countries, efforts to implement their proposals have been met with brick walls. The Objective of this conceptual paper is to emphasis the need for Healthcare providers to be involved in Policy making in their countries, to champion health care policies that will improve health care delivery. **METHODS:** Using Nigeria as case study. I sort the views of several health professionals through their articles on Improving Healthcare delivery in Nigeria published in popular Journals and magazines. I consulted magazines and Journals from more advanced countries to seek out ways through which they have improved their health care system. **RESULTS:** Of all the views presented by these health professionals (Pharmacist and Medical Doctors), most pointed towards the role of the government in improving the healthcare sector, others suggested a need for health professionals to be involved in Politics without emphasizing on it. While in my analysis of the systems in the developed countries, I discovered that healthcare providers were involved in the government not as executive but as legislatures, this way they sponsor health related bills and policies and were able to improve the value of healthcare delivery. **CONCLUSIONS:** To improve healthcare delivery and patient care in Africa, Health care givers (pharmacist and doctors) should be part of the countries policy makers (legislatures) so as to drive the needed transformation in the health sector.

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HEALTH CARE POLICY AND COST AFTER EARTHQUAKE IN NEPAL

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Nepal is a topographically vulnerable country for many life threatening disasters like earthquake, landslides, avalanche, floods etc. Health care policy should focus on the disaster management plan and quick relief programs following major disasters. According to National consensus, 8151 people have been killed and 17,886 left injured. Nepal's earthquake economic toll is massive in the health sector too. Many hospitals